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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,944	12/12/2003	Jong Kil	A03P1079US02	3701

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PACESETTER, INC.
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EXAMINER	
GREENE, DANA D	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,944	KIL ET AL.	
	Examiner	Art Unit	
	Dana D. Greene	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/12/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-~~8~~9, 10, 11, and 12 stand rejected under 35 U.S.C. §102(e) as being anticipated by Kroll et al. (US 6,813,514 B1, hereinafter "Kroll"). With reference to claims 1 and 12, Kroll is considered to disclose:

a means for sensing a cross-chamber cardiac signal using an atrial electrode and a ventricular electrode (*see* col. 8, ln. 45-67, Kroll). The disclosed atrial tip and ventricular tip electrodes are considered to anticipate the claimed atrial and ventricular electrodes because both sense atrial cardiac signals using electrodes implanted within the ventricles and ventricular cardiac signals using electrodes implanted within the atria, then combining the signals to emulate the surface EKG;

a means for distinguishing portions of the cross-chamber cardiac signal corresponding to atrial signals from those corresponding to ventricular signals (*see* col. 29, ln. 35-30, Kroll). The disclosed step of generating separate sets distinguishing between P-waves and QRS-complexes is considered to anticipate the claimed means for distinguishing portions of the cross-chamber cardiac signal because both means set

out differences between portions of the cardiac signals corresponding to atrial signals and those corresponding to ventricular signals. Further, it is know that the normal contraction of atrial heart muscle tissue appears as a P-wave and the normal contraction of ventricular muscle tissue appears as an R-wave (sometimes referred to as the "QRS complex");

a means for adjusting the relative amplitudes of the portions of the cross-chamber cardiac signal corresponding to atrial signals and the portions corresponding to ventricular signals so as to yield an emulated surface EKG (*see* col. 11, ln. 52-63, Kroll). The disclosed means of modifying the operating parameters used by the microcontroller are considered to anticipate the claimed adjustment of the relative amplitudes because both enhance the performance of emulation by the implanted device by adjusting the amplitude to improve the operation of the device.

With reference to claim 11, Kroll is considered to disclose:

sensing circuitry operative to sense a cross-chamber cardiac signal using an atrial electrode and a ventricular electrode (*see* col. 10, ln. 39-45, Kroll). The disclosed atrial and ventricular sensing circuits are considered to anticipate the claimed sensing circuitry because both configurations work to sense signals between a lead in the atria and a lead in the ventricle ("cross-chamber" sensing);

an EKG emulation unit operative to distinguish portions of the cross-chamber cardiac signal corresponding to atrial signals from those corresponding to ventricular signals (*see* col. 10, ln. 39-50, Kroll). The disclosed signals detected by the internal leads of the implanted device are considered to anticipate the claimed emulation unit

because both configurations employ devices to sense atrial and ventricular signals. Further, the Kroll reference teaches emulation performed using a matrix-based technique that emulates individual signals. This is equivalent to the EKG emulation unit because the ability to emulate individual signals must include distinguishing portions of atrial signals from ventricular signals. In this connection, Kroll is considered to disclose:

an EKG emulation unit operative to adjust the relative amplitudes of the portions of the cross-chamber cardiac signal corresponding to atrial signals and the portions corresponding to ventricular signals so as to yield an emulated surface EKG (*see* col. 11, ln. 53-64, Kroll). The disclosed modification of operating parameters is considered to anticipate the claimed adjustment of relative amplitudes because both adjustments are made to customize the operation of the device to ultimately produce an emulated EKG.

Referring to claims 7-8, Kroll is considered to disclose a method comprising controlling device functions based on the emulated surface EKG and the method of claim 1, performed entirely by the implantable medical device (*see* col. 23, ln. 13-18, Kroll). The disclosed method of using the implanted device is considered to anticipate the claimed method of using controlling device functions because both control the implanted device to begin emulation.

With regards to claim 9, Kroll is considered to disclose performance by the implantable medical device in combination with a device external to the patient (*see* col. 23, ln. 12-20, Kroll). The disclosed external programmer is considered to anticipate the

claimed external device because both work to convert internal signals into emulated EKG signals using internal signals transmitted from the implanted device.

With reference to claim 10, Kroll is considered to disclose:

The atrial electrode selected from the following group: (RA) tip, RA ring, superior vena cava (SVC) coil, left atrial (LV) ring and LV coil and wherein the ventricular electrode is selected from the following group: right ventricular (RV) tip, RV ring, RV coil, left ventricular (LV) ring (*see* col. 9, ln. 44-60, Kroll). The disclosed group is considered to anticipate the claimed group because both serve for atrial and ventricular electrode selection to achieve left and right chamber sensing, pacing and shocking.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-3 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kroll. Kroll is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed predetermined ration range of 1:4 to 1:10. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the atrial and ventricular portions so as to achieve for a predetermined ration of peak atrial to peak ventricular signal amplitudes in the range of 1:4 to 1:10, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*see* In re Aller, 105 USPQ 233).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being obvious over Kroll in view of Nataragan et al. (US 6,501,983, hereinafter "Nataragan"). Kroll is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed transition points. However, Nataragan is considered to disclose the claimed transition point (see col. 11, ln. 55-60, Nataragan). It would have been obvious to one of ordinary skill in the art to combine the teachings of Kroll with

Nataragan for the purpose of identifying ventricular depolarization and repolarization events within the cross-chamber signal.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,813,514. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to obvious variations of emulation of signals of the surface EKG and techniques to process the signals. It would have been obvious to one of ordinary skill in the art to make slight variations to the functional components of the emulation system in order to generate a combined surface EKG, as opposed to emulating each of the individual signals of the surface EKG. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-7138. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-0276.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dana D. Greene

Dana D. Greene

Ken Schaetzle
Primary Examiner
6/27/05